



STATE OF IOWA

CHESTER J. CULVER, GOVERNOR
PATTY JUDGE, LT. GOVERNOR

DEPARTMENT OF HUMAN SERVICES
EUGENE I. GESSOW, DIRECTOR

INFORMATIONAL LETTER NO. 780

TO: Iowa Medicaid Critical Access Hospital Providers

ISSUED BY: Iowa Department of Human Services, Iowa Medicaid Enterprise

DATE: January 22, 2009

RE: Utilization Control Desk Review for Critical Access Hospitals (CAH)

EFFECTIVE: January 2009

Informational Letter No. 744 was sent to all Iowa hospitals in September 2008 regarding utilization control desk review. Concerns were raised about how part 456 of the federal Medicaid regulations applied to critical access hospitals. We have further researched the regulations, and are making the following change:

All Iowa Critical Access Hospitals (CAHs) will be required to participate in IME review of their utilization control activities as required by subparts A and B of part 456 of the Code of Federal Regulations (CFR). However, the specific utilization control requirements that CAHs will have to adhere to, and will be evaluated against, are those specific to CAHs found in CFR part 485, subpart F, sections 485.635-.641, rather than those in subpart C of part 456.

Utilization control processes can be run by the state or by the individual hospitals. In Iowa, these processes are run by the hospitals, and the state has no intention of changing this process. However, the federal regulations require oversight by the state of any utilization process run by providers (as noted in Letter 744). Therefore, Iowa Medicaid Enterprise (IME) Medical Services Unit must oversee the processes that are in place for all Iowa CAHs. Desk reviews of all Iowa CAH utilization control processes will meet this requirement. But the standard IME will use for review is the CAH-specific utilization control standards in 42 CFR 485.635-.641, not those for hospitals in 42 CFR part 456, which apply to all other hospitals.

A copy of 42 CFR 485.635-.641 is enclosed for your review (Attachment 1). The IME assumes that all CAHs in the state of Iowa currently have in place structured utilization control processes.

Beginning in January 2009, a team from the Medical Services unit will assume the role of verifying the completeness of existing CAH utilization control processes. The team will consist of utilization review coordinators, program specialists, and the Medicaid Medical Director. A comprehensive baseline desk review will be completed for each CAH in the state of Iowa during 2009. Documentation from all CAHs should be forwarded to Medical Services' Hospital Utilization Review Team by April 1, 2009.

Medical Services staff will conduct a desk review of each CAH's utilization control process by utilizing a worksheet developed from the Federal Regulations to assure that each CAH in the state has documented policies and procedures in place to meet the requirements of the regulations.

Documentation that will be required to be submitted will include documentation to support these assurances. A detailed listing of the specific areas for which documentation will be required is included with this correspondence (Attachment 2). The documentation requested will enable a desk review of existing utilization policies, procedures, reporting, and current practices from the Federal Regulation in 42 CFR 485, subpart F.

After the 2009 baseline review, a desk review will be completed for each CAH in the state of Iowa every three (3) years. The schedule for the triennial review will be selected (based on the results of the baseline review) and your facility will be notified of the upcoming review seven (7) days in advance of the review.

For questions related to the desk review process, please contact the Medical Services Unit at 1-800-383-1173, extension 51341, or locally at 515-725-1341.

[Code of Federal Regulations]
[Title 42, Volume 3]
[Revised as of October 1, 2004]
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TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF
HEALTH AND HUMAN SERVICES (CONTINUED)

PART 485_CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS--Table of Contents

Subpart F_Conditions of Participation: Critical Access Hospitals (CAHs)

Sec. 485.635 Condition of participation: Provision of services.

(a) Standard: Patient care policies. (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of Sec. 485.631(a)(1); at least one member is not a member of the CAH staff.

(3) The policies include the following: (i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of Sec. 483.25(i) is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

(b) Standard: Direct services--(1) General. The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) Laboratory services. The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

- (i) Chemical examination of urine by stick or tablet method or both (including urine ketones);
- (ii) Hemoglobin or hematocrit;
- (iii) Blood glucose;
- (iv) Examination of stool specimens for occult blood;
- (v) Pregnancy tests; and
- (vi) Primary culturing for transmittal to a certified laboratory.

(3) Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

(4) Emergency procedures. In accordance with the requirements of Sec. 485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.

(c) Standard: Services provided through agreements or arrangements.

(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including--

- (i) Inpatient hospital care;
- (ii) Services of doctors of medicine or osteopathy; and
- (iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.
- (iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

(4) The person principally responsible for the operation of the CAH under Sec. 485.627(b) (2) of this chapter is also responsible for the following:

- (i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.
- (ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

(d) Standard: Nursing services. Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of

care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

(4) A nursing care plan must be developed and kept current for each inpatient.

Sec. 485.638 Conditions of participation: Clinical records.

(a) Standard: Records system.--(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable--

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) Standard: Protection of record information.--(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) Standard: Retention of records. The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

Sec. 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) Designation of qualified practitioners. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by--

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

(b) Anesthetic risk and evaluation. (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) Administration of anesthesia. The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only--

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in Sec. Sec. 413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(e) Standard: State exemption. (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are

effective upon submission.

Sec. 485.641 Condition of participation: Periodic evaluation and quality assurance review.

(a) Standard: Periodic evaluation--(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of--

(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

(ii) A representative sample of both active and closed clinical records; and

(iii) The CAH's health care policies.

(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) Standard: Quality assurance. The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that--

(1) All patient care services and other services affecting patient health and safety, are evaluated;

(2) Nosocomial infections and medication therapy are evaluated;

(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by--

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity; or

(iii) One other appropriate and qualified entity identified in the State rural health care plan; and

(5) (i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

(iii) The CAH documents the outcome of all remedial action.

Documentation required for the desk review will include policies and procedures for each of the following areas: (42 CFR 485 Subpart F, Sections 635-641).

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| Section: | <ul style="list-style-type: none"> ▪ Patient care policies: |
| 635(a)2 | <ul style="list-style-type: none"> • Policies are developed with the advice of a group of professional personnel that includes one or more doctors, nurse practitioners, clinical nurse specialists, and at least one member is not a member of the CAH staff |
| 635(a)3(iii) | <ul style="list-style-type: none"> • Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH. |
| 635(a)4 | <ul style="list-style-type: none"> • These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH. |
| 635(b)4(b) | <ul style="list-style-type: none"> • These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions. |
| 635(d)4 | <ul style="list-style-type: none"> • A nursing care plan must be developed and kept current for each inpatient. |
| 638(a)4(i) | <ul style="list-style-type: none"> ▪ Clinical Records - The CAH maintains a record that includes, as applicable -- <ul style="list-style-type: none"> • Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient; |
| | <ul style="list-style-type: none"> ▪ Periodic evaluation <ul style="list-style-type: none"> • The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of -- |
| 641(a)(1) | <ul style="list-style-type: none"> • The utilization of CAH services, including at least the number of patients served and the volume of services; |
| 641(a)(1)(i) | <ul style="list-style-type: none"> • A representative sample of both active and closed clinical records; and |
| 641(a)(1)(ii) | <ul style="list-style-type: none"> • The CAH's health care policies. |
| 641(a)(1)(iii) | <ul style="list-style-type: none"> • The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed. |
| 641(a)(2) | <ul style="list-style-type: none"> ▪ Quality Assurance <ul style="list-style-type: none"> • The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcome. |
| 641(a)(2)(b) | |